UNITARY SPINAL DISC IMPLANT

CROSS-REFERENCE

This application claims the benefit of U.S. Provisional Application No. 61/786,193, filed Mar. 14, 2013, which applications are incorporated herein by reference.

BACKGROUND OF THE INVENTION

Artificial disc technology has been employed as a surgical approach to repair or replace damaged spinal discs in an attempt to relieve debilitating neck and back pain, and to maintain or restore intervertebral spacing while attempting to minimize their constraining effects on the normal biomechanical movement of the spine. The quest for a more physiologic device to accomplish these goals began in the 1950s and continues to this day.

Total disc replacement is still a relatively new, promising field of spine implant technology that has the potential to revolutionize the treatment of degenerative disc disease. It is clear from both short-term in-vitro and clinical data, that disc replacements can successfully preserve the motion of a treated spine and significantly reduce the potential incidence of adjacent level disc degeneration. But unfortunately, not unlike as many as 40% of spinal fusions performed worldwide, disc replacements may also need to be revised due to poor implantation technique, component wear, or failure of the device, to name but a few.

Clinical data has illustrated that many failures occur as a result of over-aggressive bone bed preparation or excessive protuberances on the implants both of which can result in compromise of the vertebral endplates. Other data suggests that many design failures resulted from point loading or inadequate load distribution across the endplate. Still other designs suffer from poor choices of materials for articular wear bearings, oxidation, and/or inadequate long-term wear characteristics between device sub-components. Each of the aforementioned deficiencies may ultimately result in subsidence, loss of designed function, or even spontaneous fusion.

It may be a generation before sufficient data emerges to clearly delineate the long-term successful designs from the catastrophic failures, but given that most of the currently pending or recently approved artificial disc implants in the market are based on design fundamentals utilized in other orthopedic applications that have already been demonstrated to fail for predictable reasons, one might expect to see many of these designs fail in similar fashion for the same reasons. Accordingly, there remains a need for better artificial disc technology that addresses these shortcomings by providing an artificial disc that does not significantly inhibit spinal movement, minimizes any potential for wear between disc components and or vertebral bodies, improves upon the surgical technique utilized to implant them, reduces the potential for histocytic foreign body and/or inflammatory response, and provides physiologic load bearing and joint spacing functions akin to the normal, healthy spinal disc. In addition, there also remains a need for better salvage and fusion devices to replace other failed artificial discs.

SUMMARY OF THE INVENTION

A unitary intervertebral device, having no independent moving components is provided for non-fusion articulation applications. The interbody articulating device allows for limited flexion and rotation between adjacent vertebrae, helping to preserve or restore near-normal motion between adjacent vertebrae. Rotational motion is achieved around one or more protrusions incorporated into the spinal interbody device.

In one aspect the invention is an implant comprising a unitary structure, having no independent articulating components, containing integrated features to replace the articulating function of the natural spinal disc, and allowing a spinal joint into which it has been implanted, to closely approximate the flexion biomechanics and rotational motion of a reasonably healthy joint.

It is another object of this invention to provide a highly polished, high wettability surface finish to the arcuate surface(s) of a discus-shaped implant which makes broad contact with the endplates of the vertebral bodies in order to improve rotational motion with reduced friction and wear.

It is another object of this invention to significantly reduce or eliminate 3rd body wear particles resulting from rolling or sliding friction between the articulating surfaces of an artificial disc and the vertebral endplates and/or endplate cartilage of the spine.

It is another object of this invention to significantly reduce or eliminate any 3rd body wear particles resulting from micromotion or sliding friction between assembled sub-components of the artificial disc such as between a poly bearing surface and an endplate to which it may be captured, fixed or otherwise assembled.

It is another object of this invention to maximize the surface area coverage of the vertebral endplate with the implant, to minimize the potential for implant subsidence, spontaneous fusion, and localized compression stresses.

It is yet another object of at least one variation of this invention to preserve as much native endplate cartilage as possible to promote and improve articulation between the vertebra and the implant, rather than intentionally removing native cartilage and abrading endplate surfaces to induce bone ingrowth and fusion to the implant on one or both adjacent endplate surfaces, as is done with other spinal disc replacements.

In one articulating form, a first protrusion extends perpendicularly from the superior (first) aspect of a discus-shape of the interbody device to form a spike or rotational protrusion, while a second protrusion extends axially from the inferior (second) aspect of the interbody device to form a second spike or rotational protrusion. Protrusions preferably extend perpendicularly from the apex of both the first and second arcuate articulating surfaces about the central axis.

In another form, a single protrusion extends axially from the superior aspect of the interbody device to form a spike, pivot point, or anchoring protrusion, while the inferior surface is a slightly rounded articulating bearing surface. One or both of the first and/or second arcuate surfaces may be highly polished.

In yet other variations, the implant is configured to provide a polished articulating surface on one bearing surface and a fusion surface on the opposite bearing surface.

In other articulating and non-articulating forms, tether features are described for providing ingrowth through the endplate to an adjacent vertebral body.

In still other configurations, variations of a unitary device are described comprising an intermediate core that is permanently affixed between the outer articulating bearing surfaces, to act as an alternative cushioning apparatus, providing a dampening feature for the spine in place of the defective natural spinal disc. Both articulating and fusion versions of the device are described.

Numerous geometries are described to define functional profiles of the disc replacement implant which may be uti-